

JUL 30 2012

**510(k) Summary**

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Date Prepared: 05/11/2012

DEVICE INFORMATION

Trade/Proprietary Name: GMK Sphere
Common Name: Total Knee Prosthesis
Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

21 CFR 888.3560
Class II
Device Product Codes: JWH

Predicate Devices:

510(k)	Product	510(k) Holder
K090988	GMK Total Knee System	Medacta International
K972626	Advance Knee System	Wright Medical Technology
K972770	Advance UC Tibial Insert	Wright Medical Technology
K974328	Advance Total Knee System	Wright Medical Technology
K991052	FS 1000 Knee System	Renaissance Instruments, LLC
K081023	Evolis Total Knee System	Medacta International
K102437	GMK Total Knee System- Revision	Medacta International
K103170	GMK Revision SC Liners	Medacta International
K113571	GMK Resurfacing Patella Size 4	Medacta International

Product Description

The GMK Sphere Total Knee System allows for medial-pivot rotation of the knee joint and is comprised of the following components:

- Femoral Component Left and Right, Sizes 1-7
Co-Cr-Mo (ISO 5832-4)
- Tibial tray fixed cemented Left and Right, 4 intermediate sizes
Co-Cr-Mo (ISO 5832-4)
- Tibial Insert Fixed Flex and Congruent, Left and Right, Sizes 1-6, 10mm-20mm
UHMWPE (ISO 5834 -2) Type 1, Ti6Al4V (ISO 5232-3)

The following components of the GMK Sphere have been previously cleared:

- Resurfacing patella Sizes 1-4 (K090988 and K113571)
- Tibial tray fixed cemented Left and Right, Sizes 1-6 (K090988)
- Primary extension stem Ø11mm / L 65 mm (K090988)

Indications for Use

The GMK knee prosthesis is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Avascular necrosis of femoral condyle.
- Post traumatic loss of joint configuration.
- Primary implantation failure.

Tibial augments are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.

In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components.

Comparison to Predicate Devices

The indications for use of the GMK Sphere are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the GMK Sphere are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

The GMK Sphere was tested for the following compared to the predicate devices:

- Instability due to design and surface area
- Constraint measurements
- Contact pressures and areas
- Dynamic physiological loads
- Modular connection
- Range of Motion ASTM 2083

A review of the mechanical data indicates that the GMK Sphere is equivalent to devices currently cleared for use and is capable of withstanding expected in vivo loading without failure.

Conclusion:

Based on the above information, the GMK Sphere can be considered as substantially equivalent to its predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

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Medacta International
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Mr. Adam Gross
Director of Regulatory and Quality
4725 Calle Quetzal, Unit B
Camarillo, CA 93012

Re: K121416

Trade/Device Name: GMK Sphere

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained
cemented prosthesis

Regulatory Class: Class II

Product Code: JWH

Dated: May 11, 2012

Received: May 11, 2012

Dear Mr. Gross

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

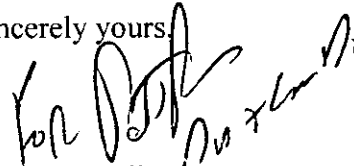
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson

Director

Division of Surgical, Orthopedic,
and Restorative Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121416

Device Name: GMK Sphere

Indications for Use.


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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K 121416

Prescription Use x
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)